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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,131	12/05/2001	Geoffrey Goldspink	10103-004	8321

20583 7590 10/24/2006

JONES DAY  
222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER
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HAMA, JOANNE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	10/005,131	GOLDSPINK, GEOFFREY	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 02 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 02 October 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 31-35, 40-42, 51, 58-62, 67-69, 78, 97 and 98.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

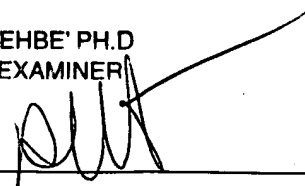
#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

ANNE M. WEHBE' PH.D  
 PRIMARY EXAMINER



Continuation of 3. NOTE: The scope of the genomic sequence in claims 41, 42, 68, 69 has expanded from mammal/fish to homologs of eukaryotic sequence. This is a new issue of consideration.

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Applicant filed a response to the Final Rejection of April 4, 2006 on October 2, 2006. Because the claims have not been entered, the claims of December 29, 2005 are under consideration.

Claims 31-35, 40-42, 51, 58-62, 67-69, 78, 97, 98 are under consideration.

**Maintained Rejections**

**35 U.S.C. § 112, 1<sup>st</sup> parag.**

Applicant indicates that the art provides support for an artisan to practice enzyme replacement therapy for Fabry disease at the time the invention was made (Applicant's response, pages 5-10). Applicant discusses that the art teaches treatment with alpha-Galactosidase A protein (e.g. Schiffmann et al.). However, as indicated in the Final Action of April 4, 2006 (pages 4-5), the results of protein therapy cannot be extrapolated to that of gene therapy. Applicant also refers to journal articles of Eng et al. and Jung et al. for providing guidance for an artisan to practice the claimed invention using viral vectors. In response, the argument as they apply to using viral vectors is not germane to the instant elected invention, which is drawn to plasmids (see Final Action, April 4, 2006, page 2, under "Detailed Action"). Applicant is reminded that should journal articles be used to cite support, that a courtesy copy be provided with Applicant's response.

As such, the rejection, as it applies to the claims remains.

**35 U.S.C. § 112, 2<sup>nd</sup> parag.**

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Applicant addresses that claims have been amended. As the amendments filed October 2, 2006 have not been entered, the arguments supporting these amendments are not considered.

**35 U.S.C. § 103(a)**

Applicant indicates that the Jeang et al. reference teaches that the CMV gene together with its promoter and spliced mRNA structure may contain all of the regulatory elements necessary for strong constitutive expression in mammalian cells. As such, the reference does not teach that the viral (CMV) promoter contains all of the regulatory elements needed for strong constitutive expression, rather a combination of the CMV gene, promoter, and spliced mRNA does (Applicant's emphasis, Applicant's response, page 10, 3<sup>rd</sup> parag.). In response, this is not persuasive. In reading the section indicated by Applicant, Jeang, page 222, lines 6-10 (see Applicant's response, page 10, 3<sup>rd</sup> parag), Jeang et al. describes the nucleic acid regions that comprise the CMV promoter (Jeang et al., page 2221, 2<sup>nd</sup> col., line 12 to page 2222, 1<sup>st</sup> col., line 6), but does not teach that there are other requirements (e.g. spliced mRNA) for gene expression. It is noted that it is unclear where in the Jeang et al. text spliced mRNA is required for transcription. As such, the rejection remains.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-

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272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file

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JH .